FDA under this part. In these instances, and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible, the agency will notify the reporting entity in writing of the additional information that is required.

(b) Any request under this section shall state the reason or purpose for which the information is being requested, specify the date that the information is to be submitted and clearly relate the request to a reported event. All verbal requests will be confirmed in writing by the agency.

§ 803.16 Disclaimers.

A report or other information submitted by a reporting entity under this part, and any release by FDA of that report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. The reporting entity need not admit and may deny that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a reportable event.

§ 803.17 Written MDR procedures.

User facilities, importers, and manufacturers shall develop, maintain, and implement written MDR procedures for the following:

(a) Internal systems that provide for:

(1) Timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements;

(2) A standardized review process/procedure for determining when an event meets the criteria for reporting under this part; and

(3) Timely transmission of complete medical device reports to FDA and/or manufacturers;

(b) Documentation and recordkeeping requirements for:

(1) Information that was evaluated to determine if an event was reportable;

(2) All medical device reports and information submitted to FDA and manufacturers;

(3) Any information that was evaluated for the purpose of preparing the submission of semiannual reports or certification; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.18 Files and distributor records.

(a) User facilities, importers, and manufacturers shall establish and maintain MDR event files. All MDR event files shall be prominently identified as such and filed to facilitate timely access.

(b)(1) For purposes of this part, ''MDR event files'' are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information, e.g., medical records, patient files, engineering reports, etc., in lieu of copying and maintaining duplicates in this file. MDR event files must contain:

(i) Information in the possession of the reporting entity or references to information related to the adverse event, including all documentation of the entity's deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part.

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that was submitted to FDA and other entities (*e.g.*, an importer, distributor, or manufacturer).

(2) User facilities, importers, and manufacturers shall permit any authorized FDA employee during all reasonable times to access, to copy, and to verify the records required by this part.

(c) User facilities shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. Manufacturers and importers shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to

the expected life of the device, whichever is greater. MDR event files must be maintained for the time periods described in this paragraph even if the device is no longer distributed.

(d)(1) A device distributor shall establish and maintain device complaint records containing any incident information, including any written, electronic, or oral communication, either received by or generated by the firm, that alleges deficiencies related to the identity (*e.g.*, labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. Information regarding the evaluation of the allegations, if any, shall also be maintained in the incident record. Device incident records shall be prominently identified as such and shall be filed by device, and may be maintained in written or electronic form. Files maintained in electronic form must be backed up.

(2) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the record.

(3) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

(e) The manufacturer may maintain MDR event files as part of its complaint file, under § 820.198 of this chapter, provided that such records are prominently identified as MDR reportable events. A report submitted under this subpart A shall not be considered to comply with this part unless the event has been evaluated in accordance with the requirements of §§ 820.162 and 820.198 of this chapter. MDR files shall contain an explanation of why any information required by this part was not submitted or could not be obtained. The results of the evaluation of each event are to be documented and maintained in the manufacturer's MDR event file.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.19 Exemptions, variances, and alternative reporting requirements.

(a) The following persons are exempt from the reporting requirements under this part.

(1) An individual who is a licensed practitioner who prescribes or administers devices intended for use in humans and who manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a ''physician-patient'' relationship.

(2) An individual who manufactures devices intended for use in humans solely for such person's use in research or teaching and not for sale, including any person who is subject to alternative reporting requirements under the investigational device exemption regulations, parts 812 and 813 of this chapter, which require reporting of all adverse device effects.

(3) Dental laboratories, or optical laboratories.

(b) Manufacturers, importers, or user facilities may request exemptions or variances from any or all of the reporting requirements in this part. The request shall be in writing and include information necessary to identify the firm and device, a complete statement of the request for exemption, variance, or alternative reporting, and an explanation why the request is justified.

(c) FDA may grant in writing, to a manufacturer, importer, or user facility, an exemption, variance, or alternative from, or to, any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time period. These modifications may be initiated by a request as specified in this section, or at the discretion of FDA. When granting such modifications, FDA may impose other reporting requirements to ensure the protection of public health.